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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,674	08/08/2006	Muthunadar P. Periasamy	1667 WO/US	4628

76656 7590 03/27/2012

Patent Docket Department
Armstrong Teasdale LLP
7700 Forsyth Boulevard
Suite 1800
St. Louis, MO 63105

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/27/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,674	PERIASAMY ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-4,6,10-20 and 27-35* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-4, 6, 10-20 and 27-35* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Applicant traverse the restriction requirement mailed on 11/09/2011 is found persuasive and restriction requirement set forth is withdrawn.
- Claims 1-4, 6, 10-20 and 27-35 are pending and presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

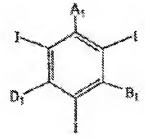
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6,10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (US 5,695,742) in view of Sovak (US 5,698,739) are withdrawn in view of amendments and arguments filed on 06/01/2011.

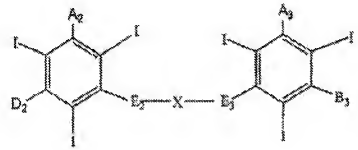
However, upon further consideration a new ground(s) of rejection is prepared as follow.

Claims 1-4, 6, 10, 13-20 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (US 5,695,742) in view of Sovak et al (US 7,250,153) and Aime et al (US 2010/0135913).

Claims are drawn to an injectable radiological composition for x-ray visualization during radiological examination, the composition comprising a mixture of at least one monomer and at least one dimmer corresponding to formula I and formula I



Formula (I)

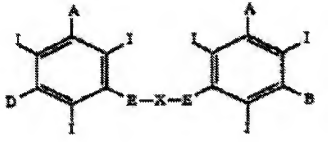


Formula (II)

wherein A1 is secondary amide, A2 and A3 are primary amide as set forth in the claim 1.

Felder teaches an injectable aqueous compositions, comprising mixtures of non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (11) contrast agents useful for x-ray imaging of human body (abstract and col. 4 lines 30-60).

type(I)



type (II)

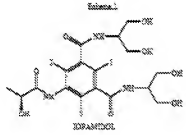
Monomer type (I) is ioversol and iohexol and dimer type (II) includes contrast agent like iodixanol, iotrol, iotasol. The performance of the compositions is increased by the addition of a series of additives, particularly stabilizers, agents controlling the dissolution, buffers (TRIS) or also biologically acceptable mineral salts like phosphates, tromethanol, EDTA, EDTA CaNa2, heparin, hirudin, glycerol and the like (col. 9 lines 52-65+). Additional disclosure includes that injectable aqueous compositions comprising mixtures of non-ionic iodinated aromatic compounds monomer of type (I) and dimmers of type (11), not only have an intermediate osmolality compared to the pure solutions of (I) and (11), and are also isoosmolol or isotonic to the plasma but they also have a

lower viscosity than the expected, and a lower toxicity than those shown by the corresponding pure solutions of (I) and (11).

Felder fails to incorporate specific dimer of formula (type II) i.e., iosmin (also known as iosimenol) and monomer such as iopamidol.

Sovak discloses dimeric non-ionic radiographic contrast media (RCM) such as iosimenol for improving biological tolerance by formulating such media in buffers containing organic amines and carboxylic acids (abstract). Additional disclosure includes that in addition to iosimenol, other dimeric radiographic contrast agents can advantageously be formualted using the buffer systems. Other such dimeric RCM include oidixanol, iotrolan and the like.

Aime discloses the use of radiographic contrast agents formulations for the x-ray and MRI diagnostics (abstract). In one embodiment the iodinated contrast agent comprising amido fucntions are the compounds of formula



IOPAMIDOL

Additional disclosure includes that the use of a iodinated contrast agent comprising at least one amido funciton for the preparation of a diagnostic formulation to obtain in vitro ro in vivo images using MRI techniques, alone or combnined with x-ray radiography.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate non-ionic iodinated aromatic compounds dimmer formula (type II) and monomer iopamidol into Felder's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Sovak teaches that dimeric non-ionic contrast media, such as iosimenol formulations containing a carboxylic acid, such as citric acid, and an amine in excess tolerated autoclave sterilization, while the systemic biological tolerance was significantly increased compared to standard formulations (Col. 1 lines 64+). Sovak furhter discloses that the novel buffer formulations improved the systemic tolerance of iosimenol in the in vivo studies and the results are directly applicable to clinical use in humans and other species (Col. 6 lines 14-19). Therefore, one of ordinary skill in the art would have a reasonable expectation of success because both Felder and cited reference teaches a injectable aqueous compositions, comprising mixtures of non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (II) contrast agents that can be used in the same field of endeavor such as water-soluble contrast media for the visualization of the interior spaces in body, such as blood vessels, body cavities, spaces in body organs, or cavities in the nervous system and for general contrast enhancement in computerized tomography.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

/J. S./
Examiner, Art Unit 1618